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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,988	08/15/2006	Alastair G. McLeod	82047003/P3139-US	8867

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Intellectual Property Dept.  
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EXAMINER
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SU, SUSAN SHAN

ART UNIT	PAPER NUMBER
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3761

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,988	<b>Applicant(s)</b> MCLEOD ET AL.	
	<b>Examiner</b> SUSAN SU	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>15 August 2006</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Status of Claims***

Claims 1-12 have been canceled in the Preliminary Amendment filed on the same date as the original application and new claims have been added.

Claims 13-32 are new and pending and examined on the merits.

### ***Claim Objections***

2. Claim 18 is objected to because of the following informalities:  
typographical error; part "d." should have been part --b.--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 20 & 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim language in both claims describes that the first passage is located adjacent to the bladder rather than inside the bladder, wherein the first passage is for supplying or removing fluid between the wound and the bladder. It is unclear to one skilled in the art how the fluid inflating media can be supplied to the interior of the bladder via the first passage, which is located outside of the

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bladder, and then have the media seep out of the bladder into the wound.

Furthermore, in Fig. 1 of the instant application, the Applicant shows a first passage adjacent to the bladder and a separate passage for supplying fluid inflating media to the inside of the bladder.

For the examination of the above claims, the Examiner assumes that the Applicant has meant to claim "a third passage" in place of "the first passage."

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 13-16, 18, & 25-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Blott et al. (US 2006/0155260, "Blott").

With regard to Claim 13, Blott teaches a wound treatment device (see Fig. 16a) comprising:

- a) a bladder (348) to be placed over and/or within a wound, the bladder being inflatable to conform to the surface of the wound;
- b) sealing means (342) for isolating the bladder from the atmosphere when placed over and/or within the wound;

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- c) a first passage (355), the first passage opening adjacent the bladder; and
- d) a suction source (18, see Fig. 1 and [0510]) connected to the first passage, whereby the suction source may apply suction to an area between the bladder and the wound and thereby drain exudates from the area.

With regard to Claim 14, Blott also teaches that the bladder has a surface with folds (352) thereon when inflated (membrane 361 line the exterior surface of the bladder and is therefore considered to be part of the bladder's surface).

With regard to Claims 15 & 16, Blott also teaches that the bladder has a convoluted outer surface with an uneven texture (membrane 361 with apertures 362, [0613]).

With regard to Claim 18, Blott also teaches:

- a) a second passage (354), the second passage opening adjacent the bladder; and
- b) a fluid rinsing media source (12, see Fig. 1) connected to the second passage, whereby the fluid rinsing media source may supply fluid rinsing media to an area between the bladder and the wound.

With regard to Claims 25 & 26, Blott also teaches that the sealing means includes a skirt extending from the bladder (see Figs. 1 & 16a) and at least a portion of the skirt bears adhesive ([0100]).

With regard to Claim 27, Blott teaches a wound treatment device comprising:

- a) a seal (3), the seal being defined by a sheet of material having opposing sides;
- b) an inflatable bladder (348) extending from at least one of the sides of the seal, whereby the seal defines a skirt extending outwardly from at least a portion of the bladder (see Fig. 16a);
- c) an inflating fluid media source (inherent for filling the 348) in fluid communication with the bladder, whereby the bladder may be inflated with inflating fluid media ([0602]).

With regard to Claim 28, Blott also teaches that at least one of the opposing sides of the seal bears adhesive ([0100]).

With regard to Claim 29, Blott also teaches a rinsing fluid media source (12) providing rinsing fluid media to at least one opening situated adjacent the bladder (354), whereby the area adjacent the bladder may be rinsed with rinsing fluid media.

With regard to Claim 30, Blott also teaches a suction source having at least one opening situated adjacent the bladder (355), whereby the suction source may apply suction to an area adjacent the bladder.

With regard to Claim 31, Blott teaches a wound treatment device comprising:

- a) a seal (3), the seal being defined by a sheet of material having opposing sides bounded by a seal perimeter;

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- b) an inflatable bladder (348) spaced inwardly from the seal perimeter, whereby the seal defines a skirt extending outwardly from the bladder;
- c) an inflating fluid media source ([0608]) in fluid communication with the bladder, whereby the bladder may be inflated with inflating fluid media; and
- d) a fluid communication passage (355):
  - 1) isolated from the interior of the bladder, and
  - 2) opening adjacent the bladder;
- e) a fluid pressure source in communication with the fluid communication passage, whereby the fluid pressure source may supply fluid to, and/or withdraw fluid from the fluid communication passage.

With regard to Claim 32, Blott also teaches that at least one of the opposing sides of the seal bears adhesive ([0100]).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blott in view of Bates et al. (US 2005/0131326, "Bates"). Blott does not expressly teach that the bladder is at least partially defined by a bellows. Bates teaches a bladder for placement inside a wound that is partially defined by a bellows (see Fig. 4, when the bladder 106 is deflated it naturally forms pleats just like a bellow). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Blott with Bates for the purpose of allowing the bladder to collapse to reduce volume and therefore adjust to the size of the wound.

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blott in view of Boynton et al. (US 6,520,982, "Boynton"). Blott does not teach a heater heating the fluid rinsing media from the fluid rinsing media source. Boynton teaches heating a liquid used for irrigating a wound. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Blott with Boynton for the purpose of making the wound treatment process more comfortable for the patient.



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11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blott in view of Palasis (US 2002/0095114). Blott also teaches that the device:

- a) further comprising a fluid inflating media source (inherent in "permit inflation of the body 348" in [0602]) connected to a third passage, whereby the fluid inflating media source may supply fluid inflating media to the interior of the bladder;

However, Blott does not teach:

- b) wherein the bladder is formed of a material which the fluid inflating media may pass through, whereby fluid inflating media inflating the bladder may permeate into the wound.

Palasis teaches a balloon with apertures on the surface so that the inflating media may pass through and permeate into the surrounding tissues ([0046-47], Fig. 12). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Blott with Palasis for the purpose of providing pressure on the tissues while delivering a therapeutic agent.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blott in view of Oyaski (US 2002/0182246). Blott does not teach that the bladder is transparent to allow for visual inspection of the wound. Oyaski teaches a bladder (28) that is transparent ([0017]) to allow for visual inspection of the wound. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Blott with Oyaski for the purpose of letting the caretaker see the healing progress of the wound.

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13. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blott in view of Prescott (US 5,989,245). Blott does not teach a light source within or adjacent the bladder, whereby the light source may photostimulate the wound surface. Prescott teaches a portable laser bandage used in speeding up wound healing. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Prescott's bandage into Blott for the purpose of stimulating cells to grown faster so the wound can heal sooner.

14. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blott in view of Alon (US 5,230,703). Blott does not teach an electrical terminal within or adjacent the bladder. Alon teaches placing an electrode inside the wound (Col. 3 lines 4-8) to stimulate blood circulation and therefore promote wound healing. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Blott with Alon for the purpose of speeding up wound healing.

15. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blott in view of Mann (US 5,385,538). Blott also teaches that the device further comprises a fluid inflating media source (inherent for inflating the bladder, [0602]) connected to a third passage, the fluid inflating media source being actuatable to supply fluid inflating media to the interior of the bladder. Blott does not explicitly teach withdrawing fluid inflating media from the interior of the bladder. Mann teaches inflating and deflating a bladder used in treating an injury for the purpose of varying the degree of compression on the wound. It would have been obvious to one of ordinary skill in the arts at the time of the invention to modify Blott with

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Mann for the purpose of speeding up the healing process without causing unbearable discomfort to the patient.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Susan Su/

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761